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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Home Mechanical Ventilators

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Home Mechanical Ventilators,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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Agency for Healthcare Research and Quality
ATTN: EPC SEADs Coordinator
5600 Fishers Lane
Mail Stop 06E77D
Rockville, MD 20857
FOR FURTHER INFORMATION CONTACT: Jenae Benns, Center for Evidence and Practice and Improvement, (301) 427-1496.

Email: epc@ahrq.hhs.gov

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Home Mechanical Ventilators*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Home Mechanical Ventilators*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://www.ahrq.gov/research/findings/ta/index.html.

This is to notify the public that the EPC Program would find the following information on *Home Mechanical Ventilators* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

- *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute All Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

I. What are the patient characteristics and/or laboratory criteria and/or target level measurable improvements considered for the initiation and continuation of noninvasive positive pressure ventilation supplied by a Home Mechanical Ventilator (HMV), Bilevel Positive Airway Pressure device (BPAP), and Continuous Positive Airway Pressure device (CPAP) in the home through a noninvasive interface for the population of patients with chronic respiratory failure due to neuromuscular diseases, thoracic restrictive diseases, chronic obstructive pulmonary diseases (COPD), or other lung diseases (cystic fibrosis, bronchiectasis)?

   A. What are the patient characteristics and/or laboratory criteria and/or target level measurable improvements (e.g. reduction in hypercapnia) considered for the initiation and continuation of noninvasive positive pressure mechanical ventilation supplied by a HMV through a noninvasive interface in the home?

   B. What are the patient characteristics and/or laboratory criteria and/or target level measurable improvements (e.g. reduction in hypercapnia) considered for the initiation and continuation of noninvasive positive pressure ventilation supplied as a BPAP through a noninvasive interface in the home?

   C. What are the patient characteristics and/or laboratory criteria and/or target level measurable improvements (e.g. reduction in hypercapnia) considered for the initiation and continuation of noninvasive positive pressure ventilation supplied as a CPAP through a noninvasive interface in the home?

II. In each of the above groups, what is the effect of HMV, a BPAP, or a CPAP use on patient outcomes, including mortality, hospitalization, admission/readmission to intensive care unit (ICU), need for intubation, outpatient visits, emergency room visits, disease exacerbations, quality of life

(QoL), activities of daily living (ADL), dyspnea, sleep quality, exercise tolerance, and adverse events?

III. What are the equipment parameters that are used in each of the above groups?

   A. What are the parameters of ventilator usage (e.g. mode as determined by trigger, control and cycling variables)?

   B. What are the equipment parameters that are necessary to achieve desired outcomes (e.g. flow capabilities, settings, etc.)?

   C. What are the parameters of prescribed patient usage (e.g. frequency of use, duration of use throughout the day, other)?

   D. In each of the above populations, what are the parameters of patient compliance with the prescribed usage of the equipment?

IV. What respiratory services, other than the technical support of the use of the prescribed equipment, are being provided to the above patients in the home (e.g. patient education, ongoing smoking cessation, respiratory therapist led home care)?

V. What are the professional guidelines and statements which address KQ 1 to KQ 4?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

Population(s)

I. Adults 18 years and older with chronic respiratory failure due to:

   A. Neuromuscular diseases

   B. Thoracic restrictive diseases (including thoracic cage abnormalities and morbid obesity)

C. Chronic obstructive pulmonary disease,

D. Other lung diseases (cystic fibrosis, bronchiectasis)

Interventions

I. Home mechanical ventilators (FDA-approved only) with or without pertinent ancillary in-home services (e.g. respiratory therapy in the home; pharmacy reconciliation; smoking cessation, etc.)

II. BPAP respiratory assist devices (FDA-approved only) w/ or w/o pertinent ancillary in-home services

III. CPAP respiratory assist devices (FDA-approved only) w/ or w/o pertinent ancillary in-home services

Comparators

I. Usual care (i.e. no mechanical ventilation/BPAP/CPAP)

II. Different type of noninvasive mechanical ventilation

III. Different modes of same equipment

IV. Other noninvasive ventilation

(Studies without a comparator treatment that evaluate the effect of a patient characteristic, laboratory criteria, ventilator parameter, or respiratory services on outcomes of interest will be included)

Outcomes

Patient-centered outcomes

I. Mortality

II. Hospitalization

III. Admission/readmission to intensive care unit (ICU)

IV. Need for intubation

V. Outpatient visits

VI. Emergency room visits

VII. Disease exacerbations

VIII. Quality of life (QoL)

IX. Activities of daily living (ADL)

X. Dyspnea

XI. Sleep quality

XII. Exercise tolerance

XIII. Adverse events

Timing

I. At least 1 month of treatment

Setting

I. Home

II. Assisted living residence

Publication time

I. From 1995

Subgroup analysis

I. Type of diseases

A. Neuromuscular diseases

B. Thoracic restrictive diseases

i. Thoracic cage abnormalities

ii. Morbid obesity

C. COPD

D. Other lung diseases (cystic fibrosis, bronchiectasis)

II. Length of treatment (1 month, 3 months, 6 months and longer)

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